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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,711	02/17/2006	Hidenori Urata	Q93208	4660

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EXAMINER	
KUDLA, JOSEPH S	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,711	URATA ET AL.	
	Examiner	Art Unit	
	JOSEPH S. KUDLA	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-17* is/are rejected.

7)☒ Claim(s) *8-15 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/11/08, 6/23/06 and 2/17/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restriction and the Preliminary Amendment

1. Applicant's election of species of the compound 4-(1-((4-methylbenzo[b]thiophen-3-yl)methyl)benzimidazol-2ylthio)butanoic acid in the reply, filed on February 11, 2008, is acknowledged. Applicant's preliminary amendment cancelling claims 29-39 and amending claim 2, filed March 3, 2008, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the election of species requirement, filed on February 11, 2008, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, the subject matter now under consideration is drawn to claims 1-6 and 7-17.

Priority

2. This application claims priority of International Application PCT/JP04/12335, filed August 20, 2004, which claims priority to Foreign Patent Application JAPAN 2003-298639, filed August 22, 2003.

3. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application fails to provide adequate support or

enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. All claims are not adequately supported or enabled by the prior-filed applications for a method of treatment.

It is noted that Applicant is not entitled to the priority date in these application for all claims in the instant claim set because the information contained within the earlier filed applications does not support the granting of an earlier filing date. Specifically, the prior filings (International Application PCT/JP04/12335 and Foreign Patent Application JAPAN 2003-298639) do not support Applicants instantly claimed invention because the prior filed applications are in the Japanese language and not understood by the Examiner. All claims are given a priority date of February 17, 2006.

[**Note**: For Applicant to have the possibility to perfect the priority date, as well as satisfy the requirements of the first paragraph of 35 U.S.C. 112, Applicant must provide an English translation of the priority document.]

Information Disclosure Statement

4. The Information Disclosure Statement (IDS) correspondences submitted by Applicant on February 17, 2006, June 23, 2006 and February 11, 2008 are acknowledged. The references have been reviewed to the extent each is a proper citation on a U.S. Patent.

5. The Information Disclosure Statement filed February 17, 2006 fails to comply

with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specifically, none of the foreign patent documents or the non-patent literature has been provided.

Claim Objections

6. Claim 17 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim 17 not been further treated on the merits.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-5 and 7-16 are rejected under 35 U.S.C. 112, second paragraph, as

being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language "a glucose intolerant improving amount" in claim 1 is indefinite. The Examiner is unable to ascertain from the instant specification what the term "a glucose intolerant improving amount" encompasses. Without further disclosure from Applicant, the phrase is unclear and confusing.

8. Claims 2-4 and 8-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an Enablement rejection.

Applicant asserts in claim 2 and by virtue of dependency in instant claim 3-4 and 8-16, the ability a "method for prevention." To prevent, as defined by Merriam-Webster Dictionary is to keep from happening or existing, which implies taking advance measures against something possible or probable. Furthermore, the definition of "to prevent" and the "act of preventing" embraces the complete 100% inhibition. Thus, the burden of enablement in the assertion of this claim is much higher than would be the case of enabling the treatment of the condition and is not achieved. As for the instant application in relation to the prior art, neither the prior art or the instant application enable for the prevention of diabetes with the elected compound. That being stated, nowhere in the instant application has the efficacy of the elected compound been

enabled to prevent the occurrence of diabetes or related complications. Since absolute success is not reasonably possible with most diseases/conditions, especially those having etiologies and pathophysiological manifestations as complex as diabetes, the specification, which lacks an objective showing that diabetes can actually be prevented, is viewed as lacking an adequate written description of the same.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-6 and 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishimura et al. (US Patent 6,410,576) in view of all Tsuchiya et al. (European

Patent Application EP 1 249 450), Iimura et al. ("Effects of Angiotensin Receptor Antagonist and Angiotensin Converting Enzyme Inhibitor on Insulin Sensitivity in Fructose-Fed Hypertensive Rats and Essential Hypertensives," 1995, AJH, Volume 8, Pages 353-357 and cited by Applicant), Ishihara et al. (WIPO Document WO01/12226 and cited by Applicant) and Nishimura et al. (WIPO Document WO 01/32621 and cited by Applicant, hereinafter Nishimura1).

Nishimura et al. teach that compounds that exhibit chymase inhibitory activity are expected to be effective at treating diabetes complications (columns 9, line 62 to column 10, line 17). Chymase inhibitor compounds are expected to be useful as drugs, particularly to be effective in treating various diseases originating from chymase such as diabetes complications (column 52, lines 17-22).

Nishimura et al. does not teach the specific diabetes complications or the underlying mechanism creating the complications. In addition, Nishimura et al. does not identify 4-(1-((4-methylbenzo[b]thiophen-3-yl)methyl)benzimidazol-2ylthio)butanoic acid as a chymase inhibitor.

Tsuchiya et al. teach benzimidizole derivatives as an inhibiting agent against human chymase activity is clinically applicable as a treating agent for various diseases associated with human chymase (page 2, paragraphs 1 and 7 and page 67, paragraph 238). Tsuchiya et al. teach that the benzimidizole derivatives have an extremely high chymase inhibitor activity and that one such disclosed derivative is 4-(1-((4

methylbenzo[b]thiophen-3-yl)methyl)benzimidazol-2ylthio)butanoic acid (page 2, paragraph 5 and Page 8, compound 56 and Example 15, page 64).

Iimura et al. teach an ACE inhibitor improves insulin-resistant glucose uptake (insulin sensitivity) in the insulin-resistant hypertensive rat model and essential hypertensives (Abstract).

Ishihara et al. teach that compounds having a chymase inhibitory effect are expected to be a treatment of diseases such as diabetic retinopathy (Abstract).

Nishimura1 teaches chymase compounds that exhibit excellent inhibitory activity are useful as therapeutic drugs to treat complications of diabetes and obesity (Abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention, that if chymase inhibitors in general were effective at treating complications of diabetes as disclosed by Nishimura et al. and one had a compound such as 4-(1-((4-methylbenzo[b]thiophen-3-yl)methyl)benzimidazol-2ylthio)butanoic acid which is taught by Tsuchiya et al. as having extremely high chymase inhibitor activity, the compound taught by Tsuchiya et al. would also treat diabetes complications.

It would have been obvious to one of ordinary skill in the art at the time of the invention, that in treating the complications associated with diabetes, one would also inherently treat the underlying cause of diabetes which would be the insulin resistance and associated glucose intolerance. See MPEP 2112.01 II, "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the

identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990), and, as such, it would be expected that a compound that treated diabetes complications would have to treat the underlying cause of diabetes, like glucose intolerance. Therefore, absent evidence to the contrary from Applicant, the method taught by Nishimura et al. in view of Tsuchiya et al. and that disclosed by Applicant will possess the same effect since identical products cannot have mutually exclusive properties. Therefore, Nishimura et al. in view of Tsuchiya et al, renders instant claims 1-3 and 8-16 obvious.

It would have been obvious to one of ordinary skill in the art at the time of the invention, that if ACE inhibitors are effective at improving glucose intolerance as is taught by Iimura et al. and chymase inhibitors, such as the compound taught by Tsuchiya et al., are effective at improving glucose intolerance, then a combination of the two inhibitors would be similarly effective at treating glucose intolerance. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). These combined findings render claim 7 obvious.

It would have been obvious to one of ordinary skill in the art at the time of the invention, that the combined teachings of Nishimura1 and Ishihara et al., which explicitly disclose that chymase inhibitors are useful in the treatment of complications of diabetes, obesity and diabetic retinopathy, would render instant claims 4 and 5 obvious.

Therefore, the teachings of Nishimura et al., in view of all Tsuchiya et al., Iimura et al., Ishihara et al. and Nishimura1 would render the instant invention obvious.

No claims allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-3288. The examiner can normally be reached on 9am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph S. Kudla/
Examiner, Art Unit 1611
May 5, 2008

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615